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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,526	02/26/2002	Helmut Heide	930008-2066	1405

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EXAMINER

GROUP, KARL E

ART UNIT	.PAPER NUMBER
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1755

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,526

Applicant(s)

HEIDE ET AL.

Examiner

Karl E. Group

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-24-05, 4-13-05</u> . | 6) <input type="checkbox"/> Other: _____ |

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Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2-24-05 has been entered.

Claim Rejections - 35 USC § 102 and 103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Takagi et al (5,141,510).

Takagi et al teach a sintered tricalcium phosphate (column 2, lines 10-12) having tubes of a diameter of .1-2 mm and spherical pores of 50-60 micrometers and a porosity of .5-40%. (column 2, lines 1-9, as well as figures 1A-2). It is noted that claim 3 is generic as to the phase of the final bone material.

The claims are considered anticipated or in the alternative the subject matter as a whole would have been obvious to one having ordinary skill in the art at the time of the invention to have selected the overlapping portion of the range disclosed by the prior art because overlapping ranges have been held to be a prima facie case of obvious, see *In re Malagari*, 182 U.S.P.Q 549.

4. Claims 1-20 are rejected under 35 U.S.C. 102(a or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Imura et al (6,340,648) and de Bruijn et al (6,511,510).

Imura et al teach a tricalcium phosphate sintered body (column 4, lines 46-50) having a porosity of 55 to 95% and having a interconnecting porosity of greater than 50 microns and a pore diameter of greater than 150 microns (column 2, lines 40-49).

De Bruijn et al teach sintered tricalcium phosphate bodies (column 4, lines 8-10) with a total porosity of 20-90% and macropores of .1-1.5 mm and micropores of .05-20 microns. The sintered crystals are of .05-20 microns (column 2, lines 29-34). It would be expected the porosity is interconnected due to the bone growth in the implants (column 6, lines 37-43).

The terminology "generally tubular", and "generally perpendicular" are considered qualitative and not considered to limit the claimed porosity to a specific structure. It is not clear how tubular the porosity must be to be generally tubular. Absent tangible evidence to the contrary the sintered articles are considered to possess the claimed particle diameter.

It is well settled that when a claimed composition appears to be substantially the same as a composition disclosed in the prior art, the burden is properly upon the applicant to prove by way of tangible evidence that the prior art composition does not necessarily possess characteristics attributed to the CLAIMED composition. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Circ. 1990); In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980); In re Swinehart, 439 F.2d 2109, 169 USPQ 226 (CCPA 1971).

5. Claims 1-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Takagi et al (5,531,794)

Takagi et al teach a sintered tricalcium phosphate article (column 2, lines 27-30) including tubular pores of .6-1.2 mm (see column 3, lines 49-51) and pores of 10 to 450 microns and micropores of .01-.5 microns which connect the tubular pores (see column 2, lines 15-26 and the drawings. The tubular pores may be perpendicular (column 4, lines 1-10).

The claims are considered anticipated or in the alternative the subject matter as a whole would have been obvious to one having ordinary skill in the art at the time of the invention to have selected the overlapping portion of the range disclosed by the prior art because overlapping ranges have been held to be a prima facie case of obvious, see In re Malagari, 182 U.S.P.Q 549.

6. Claim 1-20 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DE 3810803.

The German document teaches a synthetic bone material including a porous structure, see figure 2b. The material is a calcium phosphate having a CaO:P₂O₅ ratio of 3:1, calcium triphosphate (see abstract).

It is well settled that when a claimed composition appears to be substantially the same as a composition disclosed in the prior art, the burden is properly upon the applicant to prove by way of tangible evidence that the prior art composition does not necessarily possess characteristics attributed to the CLAIMED composition. In *re* Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In *re* Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980); In *re* Swinehart, 439 F.2d 2109, 169 USPQ 226 (CCPA 1971).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-87 of copending Application No. 10085526. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the copending claims overlap.

One of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the structural features taught by the copending application overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages”, In re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In re Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl E. Group whose telephone number is 571-272-1368. The examiner can normally be reached on M-F (6:30-4:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Karl E Group
Primary Examiner
Art Unit 1755

Keg
5-19-05